THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

Office of the President

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August 31, 2006

The Honorable Tom Coburn
Subcommittee on Federal Financial Management
Attn: Anna Shopen
439 Hart Senate Office Building
Washington, DC, 20510

Dear Chairman Coburn:

Thank you for the opportunity to respond to your request regarding federal earmarks received by The University of Texas M. D. Anderson Cancer Center (M. D. Anderson). We appreciate your role as guardian of federal tax dollars and we are confident you will find that these funds are accelerating M. D. Anderson's ability to achieve its mission: to eliminate cancer in Texas, the nation and the world through outstanding programs that integrate patient care, research and prevention, and through education for undergraduate and graduate students, trainees, professionals, employees and the public.

Below are responses to your questions. Please note that the summary of federal earmarks includes the number of publications due to the length of appropriate references. We would be pleased to forward the full documents if necessary.

1) Please provide a list of all appropriations received by your institution from the year 2000 to present, and the amount of assistance received.

   Please see attached summary.

2) Please provide a summary of the specific objectives or goals to be achieved by any entity, program, project or service associated with an appropriations at your institution, and for each appropriation, a list of accomplishments that can be attributed to the project, entity, program or service (e.g. published peer-reviewed research, etc., depending on the nature of the earmarks your institution has received).

   Please see attached summary.

3) How does your institution set a measure for standards to achieve quality and outcomes for entities, programs, projects or services receiving assistance through earmarks or appropriations?

   There are a number of measures utilized in academic medical centers to assess the quality and outcomes of their research programs. The attached summary describes some of these, including:

   Many of the programs receiving federal funding also apply for institutional research grants, which is a peer-reviewed process.

The programs all also have external, peer-reviewed funding, such as PO1s, SPOREs, etc.

The number of publications related to the ongoing research in peer-reviewed journals is an important measure.

The faculty are periodically reviewed by the Promotion and Tenure Committee, where attributes including the quality of their research is assessed.

4) Does your institution have a stated policy regarding Congressional earmarks or appropriations (if so, please describe)? Does your institution have a policy regarding partnering in research projects with other universities who may have a differing policy?

The institution does not have a stated policy regarding Congressional earmarks.

5) Has your institution considered hiring a lobbyist to assist your institution in attaining familiarity with the opportunities that may exist to obtain Federal funds for research – such as the earmarking process?

The institution employs a registered lobbyist, Timothy Rupli with Rupli and Associates, who is focused on the Lung Cancer Program earmark.

In conclusion, and in response to question six, M. D. Anderson finds that Congressionally earmarked funds contribute substantially to the institutional mission. As a leader in translational research, M. D. Anderson is focused on rapidly converting basic science discoveries into the most advanced technologies and therapies for diagnosis, prevention and treatment of cancer. These federal appropriations are essential seed funds that allow the institution to accelerate and expand its efforts in the areas targeted by earmarks. Through significant outreach efforts and collaborations, M. D. Anderson is also deploying knowledge about the many diseases of cancer to improve health in medically underserved populations.

I hope this information is helpful in your understanding of M. D. Anderson's use of federal appropriations. Please do not hesitate to contact me at 713-792-6000 if you or your staff have questions or need any additional information.

Sincerely,

John Mendelsohn, M.D.
President

Attachment

cc: Senator Kay Bailey Hutchison
Senator John Cornyn
Kenneth Shine, M.D.
William Shute
Margaret Kripke, Ph.D.

The University of Texas M. D. Anderson Cancer Center
Summary of Congressional Earmarks
Fiscal Years 2000 through 2006

Program Name – Lung Cancer Program -- includes 5 specific projects:

- Biology, Education, Screening, Chemoprevention and Treatment (BESCT)
- Translational Approaches for the Reversal, Genetic Evaluation and Treatment of Lung Cancer (TARGET)
- Vanguard Investigations of Therapeutic Approaches to Lung Cancer Program (VITAL)
- Imaging and Molecular Markers for Patients with lung Cancer: Approaches with Molecular Targets, Complimentary, Innovative and Therapeutic Modalities (IMPACT)
- Biomarker-based Approaches of Targeted Therapy for Lung Cancer Elimination (BATTLE)

Appropriations – All Department of Defense (DoD)

FY 2000	$7 million
FY 2001	$4.5 million
FY 2002	$3.5 million
FY 2003	$9 million
FY 2004	$9.5 million
FY 2005	$9.5 million
FY 2006	$6.7 million

Program description – Lung cancer is the most deadly cancer in the world and the leading cause of cancer-related deaths. In 2006, there will be an estimated 174,470 new cases of lung cancer and 162,000 deaths in the U.S. The year survival rate of patients with lung cancer is extremely poor at less than 16%, progress improvement of only 9% in the last 40 years. Clearly, new therapeutic approaches are desperately needed to improve patient survival.

Appropriated funds over the past seven years have been allocated to five broad areas:

Infrastructure: Complex clinical trials need support from people trained as physician-scientists, quality assurance coordinators, data analysts, research nurses, laboratory technicians, etc.

Molecular Pathology Laboratory and Serum and Tissue Bank: DoD funding has been leveraged to create a state of the art molecular pathology laboratory and recruit a prominent physician leader for the lab. Funds were used to purchase specialized immunohistochemistry and immunofluorescence equipment. The Serum and Tissue Bank allows for the utilization of large patient populations to look for biomarkers for diagnosis, prognosis and response to treatment. These resources now include a specimen and data resource for epidemiological studies with demographics and genomics profiles.

Biotstatistics and Data Management: DoD funding has enabled us to hire two outstanding biostatisticians to support the lung cancer research program and create a Biostatistics and Data Management Core. They have developed a decision analytical model for effects on quality adjusted life years; developed innovative methods for biomarker interactions, and developed novel clinical trial methods.

Career Development: The future of cancer research requires training the next generation of thought leaders. Funding has also been used to provide Career Development Awards to promising young fellows and junior faculty and to provide them with strong mentorship.

Science Day: In order to share the promising research findings acquired through this program in the past 5 years, a Science Day for Lung Cancer Research was organized in December 2005. The symposium brought together a national audience of basic scientists, translational researchers, physician-scientists, epidemiologists, and officials from the Department of Defense.

Collaborations - 15 departments at M. D. Anderson, and 6 other institutions (nationwide) collaborate on lung cancer programs receiving DoD funding.

M. D. Anderson is developing a secure web-based, internet-driven database network for interactions between all cancer institutes studying lung cancer with DoD funding.

Human Bronchial Epithelial Cell lines developed in the program are being deposited in the American Type Culture Collection for worldwide distribution.

Leveraged Dollars - The Lung Cancer Research Program has successfully more than doubled the DoD investment with more than $52M in NCI and private sector grants.

Research Accomplishments - All of the research accomplishments are too lengthy to report in details, but we can provide additional information if the Committee desires:

Manuscripts published:	97
Manuscripts in progress:	32
Abstracts:	58
Patents:	6
Project-generated grants:	NIH UO1
	MD Anderson Institutional Research Grants
	NCI PO1 (2)
	NCI RO1 (2)
Clinical Trials Designed	2

In summary, over the past seven years, the M. D. Anderson Congressionally Directed Lung Cancer Research Program has matured, beginning with BESCT having a simple schema with three basic research projects, TARGET with 10 seed projects, moving to integrated translational research programs VITAL, IMPACT, and BATTLE. In addition,

solid infrastructure has been established to fully support our research initiatives and clinical trials including the highly organized Administration Core, the Biostatistics and Data Management Core, the Molecular Pathology and Specimen Procurement Core, and the Imaging Core. With the long history of biological research and chemoprevention of lung cancer at M. D. Anderson Cancer Center supported by our National Cancer Institute (NCI) Lung Cancer SPORE, Lung Cancer Program Project Grants (P01), and Cancer Center Core Grant (CCSG)-Lung Cancer, this Congressionally Directed Lung Cancer Research Program has complemented and greatly strengthened our already existing lung cancer research program.

Program Name – George and Cynthia Mitchell Basic Science Research Building (BSRB)

Appropriations –
Department of Health and Human Services

FY 2002	$2 million
FY 2003	$2 million
FY 2004	$2 million

Program description – The $222 million George and Cynthia Mitchell Basic Sciences Research Building opened in March of 2005 as a state-of-the-art facility for laboratory research. The research conducted in the Mitchell BSRB falls into several categories: biochemistry, molecular genetics, epidemiology, neurosurgery, neuropathology and neuro-oncology. The building contains cutting-edge labs and a modern vivarium that provides the cleanest environment possible for small animal research. The building's six floors of lab research space give researchers access to imaging equipment, environmental rooms, a tissue culture room, and rooms housing fruit flies and frogs used in research. Each floor has a centrally located area, known as shared support space that reduces duplication of equipment. In addition, the fifth floor has a centralized facility in which all glassware equipment can be washed and sterilized. The building also includes a high-tech vivarium for small animal research. The vivarium employs such technology as cages individually ventilated with HEPA-filtered air (high-efficiency particulate air) to keep the environment as clean as possible. Other features include automated watering, a vacuum bedding system, a cage washer system and decontamination sterilizers. Between each research and vivarium floor is an interstitial floors housing plumbing, air circulation piping and wiring. To accommodate the needs of researchers and the ever-shifting direction of research, the interstitial floor above each lab area allows for lab infrastructure modifications without disrupting the activities below.

M. D. Anderson Cancer used the congressionally appropriated money to purchase equipment for the state-of-the-art vivarium and for mobile lab equipment to maximize the flexible design of the Mitchell BSRB. All of the vivarium equipment is used to assist all researchers who access the vivarium as these types of equipment support the husbandry of the animals. The mobile benches are used by all researchers within the building, both on the lab floors and in the vivarium, as benchtops for setting up research assays, tabletop research equipment, and as laboratory write up spaces. Since they are completely mobile, researchers are able to customize their own space for the adaptability of changing research needs without undertaking costly renovations.

Leveraged Dollars – 2001 Extramural Research Facilities Construction Project grant from the National Center for Research Resources, $2 million; $75 million in philanthropy

Program Name - Center for Research on Minority Health (CRMH)

Appropriation -

Department of Health and Human Services	
FY2000	$500,000
FY2001	$850,000
FY2002	$450,000
	$290,000*
FY2003	$500,000
FY2004	$200,000
FY2005	$500,000
Department of Defense	
FY 2006	$500,000

(* In addition to the $450,000 appropriated for the CRMH, $290,000 in FY 2002 was designated for the Prostate Outreach Project (POP)

Program Description - In 1999, Congress provided funds for the creation of the CRMH. The uniqueness of the CRMH lies partly in its guiding principles which emphasize the related themes of advancing the scientific research base as it pertains to health disparities, involving the affected populations in determining research priorities, and communicating research findings to all stakeholders. Current research within the CRMH focuses on nutritional and environmental impact studies. In addition, the CRMH sponsors several scientific working groups comprised of M. D. Anderson physicians and researchers. These working groups identify ongoing research at M. D. Anderson that pertains to minority and medically underserved populations and suggest topics to be included in M. D. Anderson's research agenda. The community outreach products developed by the CRMH will be beneficial to all areas of the United States.

The CRMH is also devoted to training graduate students and postdoctoral fellows and providing support to faculty members interested in addressing health disparities issues. As such, the CRMH and the Texas Program for Society & Health at Rice University have created the Health Disparities Research, Education, and Training Consortium. We are very interested in working with faculty to address recruitment and retention issues as they pertain to minorities and medically underserved populations. Several CRMH researchers are members of The University of Texas Graduate School of Biomedical Sciences and participate in a number of graduate training programs.

Collaborations - The CRMH has broad research and, importantly, community collaborators, including: In Houston - Asian American Health Coalition, Mayor's Office, Sisters Network, Office of Immigration and Refugee Affairs, St. Joseph Hospital, Wheeler Avenue Baptist Church, Hispanic Cultural Institute, SW Memorial Physicians Association, Harris County Public Health; **Outside of Houston** - Texas Higher Education Coordinating Board; Susan G. Komen Foundation; Centers for Medicare and Medicaid Services; Morehouse School of Medicine; ExxonMobil; Pink Ribbon Project; Prairie View A&M; Centers for Disease Control.

Leveraged Dollars - Since its creation with $500,000 in federal funding, the CRMH has successfully competed for more than $15,000,000 in grants from government and private agencies.

Research and Outreach Accomplishments - There have been many accomplishments and we will highlight some from the areas of infrastructure, community outreach, research, training, and education.

The CRMH has developed an internal infrastructure to develop culturally competent research, training and educational programs addressing health disparities.

The CRMH has developed an active and highly productive network of community- based organizations; government agencies; research, educational, and medical institutions that address the disproportionate rates of cancer incidence and mortality in the Houston area through educational outreach, research, and procurement of needed services.

The CRMH also began the Health Disparities Education, Awareness, Research and Training (HDEART) Consortium, to share resources to develop academic research and educational programs related to health disparities. The HDEART Consortium has 23 member institutions and will soon expand to 26.

The CRMH successfully competed for one of six demonstration projects funded by CMS to investigate facilitated cancer screening services and patient navigation for Hispanic Medicare beneficiaries.

Five West African, three Vietnamese, and two Chinese churches, mosques and/or temple congregations were chosen to participate in the "Pink Ribbon Project 2004," throughout the month of October, in recognition of Breast Cancer Awareness Month. The project reached approximately 5,000 people with this first-time effort through the distribution of breast cancer educational materials and a baseline access survey. The project was a joint effort sponsored by Project EXPORT and the Federal Drug Agency.

The Prostate Outreach Project (POP) is a prostate cancer screening program targeted for African Americans and other minorities in the Houston metropolitan area, including use of a mobile screening clinic. In addition to the screening aims, education and research regarding increasing knowledge and awareness, and effective communication strategies, are also being undertaken. Over 1,000 men were screened this past year with the mobile POP clinic.

We implemented the PIPELINE Scientific Training Program, linking training from kindergarten level to elementary, middle school and high school levels to undergraduate and graduate levels to postdoctoral programs. To date stipends and/or other educational training and support has been provided for approximately 15 high school students, over 25 graduate and postgraduate students, and more than 10 visiting scientists, clinical observers, and adjunct faculty, almost all of whom are from underrepresented ethnic minority communities, and who directly participate in our research projects and

community outreach activities. We are tracking these students as they make their way through the health sciences and follow up with them to encourage their professional growth.

The CRMH is one of 8 national training sites for Kellogg Scholars in Health Disparities, having just sponsored two Health Disparities Fellows for 2004 - 2006. Two additional scholars have been identified for 2006 through 2008.

Publications -

Manuscripts published:	15
Abstracts:	8

Program Name - Alliance for NanoHealth (ANH) (collaboration of Rice University, Baylor College of Medicine, The University of Texas M. D. Anderson Cancer Center, The University of Texas Health Science Center at Houston, The University of Texas Medical Branch at Galveston, Texas A&M University System Health Science Center and The University of Houston)

Appropriations –
FY2005*

Department of Defense	$2.8 million
Department of Energy	$0.6 million
National Aeronautics and Space Administration	$2.0 million
Health Resources and Services Administration	$1.0 million

(*FY 2005 Total funding for M. D. Anderson collaborative grants -- $ 653,422)

FY 2006**

Department of Defense	$2.1 million
National Aeronautics and Space Administration	$4.0 million

(FY2006 M. D. Anderson is scheduled to receive $300,000 for the purchase of an advanced optical imaging system that will have shared use with the other members of the ANH.)**

The $2.8 million included in the FY 2005 Department of Defense bill was designated for competitive interdisciplinary research projects studying the environmental, economic, social, and ethical aspects of nanotechnology. This innovative seed grant initiative was established to support proposals in the field of nanotechnology relating to health issues. The objective is to bring advancements in nanotechnology such as nanomaterials, tools, devices, fabrication, analytics, monitoring, sensing, modeling, etc. toward solutions for clinical needs. In addition to regional peer review, the projects receive external peer review from the Department of Defense through its Telemedicine and Advanced Technology Research Center (TATRC) and its external review contractor, the American Institute of Biological Sciences (AIBS). M. D. Anderson will participate in six projects that will receive funding:

Project Title	Institutions (Principal Investigator and co-Principal Investigator)
Biomodally-targeted, Magnetically-responsive Nanoparticles as Drug Carriers	MDACC/ UTHSC/ UTMB/ Aptamed/ NBMI
On-command Control of Blood Pool Residence Time for Nanoparticle-based Molecular Imaging	MDACC / UTHSC
Nanorods-mediated Gene Therapy in Bladder Cancer	MDACC / Rice

Project Title	Institutions (Principal Investigator and co-Principal Investigator)
Feasibility of Selective Laser Elimi-nation of Leukemia Cells Targeted with Gold and Silver Nanorods	MDACC / Rice / Fairway Medical
Guided Microvascular Formation and Cellular Infiltration for Tissue Regeneration Applications in Nano-Structured Silk Fibroin-Chitosan Scaffolds	MDACC / Rice
Nanomagnetic Biosensor for Cancer Diagnosis	UH /MDACC

In FY 2006, M. D. Anderson is scheduled to receive $300,000 for the purchase of shared equipment. An advanced optical imaging system will be purchased and its use will be shared with other members of ANH.

Program description - The ANH is one of the nation's leading institutional collaborations dedicated to applying nanotechnology to solve some of medicine's most compelling questions. Principle to the mission of the ANH is facilitating the translation of nanotechnology from the laboratory to clinical practice. With seven Texas institutions of higher education, the Alliance is striving to bring to the commercial marketplace next-generation healthcare technologies such as targeted therapeutics, smart drug delivery devices, and highly sensitive diagnostics.

The potential applications of nanotechnology in medicine, which include treatments for the most lethal and disabling illnesses in the world such as cancer, heart, and infectious diseases are generating the most excitement. Such medical breakthroughs have the potential to detect diseases and illnesses at much earlier stages, provide patients with safer and more effective treatments, and ultimately save lives. Many of these potential breakthroughs can be achieved through the use of nanotechnology.

The ANH benefits from Houston's world-renowned strengths in nanotechnology and medicine. With more than 5.5 million patient visits each year, the Texas Medical Center is the world's largest medical complex, consisting of 42 member institutions that are home to more than 4,000 doctors, 11,000 registered nurses, and 22,000 students. Located within three miles of the Texas Medical Center facilities are Rice University and the University of Houston, two of the leading science & engineering institutions in the nation. This close proximity of the fundamental scientific resources- where nanotechnologies are principally developed- and the medical facilities- where these nanotechnologies are further tested for translation to the clinic- provides a unique, unparalleled environment that reduces the time-to-market for biomedical nanotechnologies.

The Alliance has the potential to provide significant medical breakthroughs in disease diagnosis, treatment, and prevention. For example, advances in medical diagnostics may

include high-throughput arrays for screening blood markers before the onset of physical symptoms or using molecular imaging agents to find diseased sites in the body and subsequent detection using non-invasive imaging. Advances in treatment may include targeted delivery of therapeutic agents to disease sites and personalized drug design based on an individual's cellular makeup (to minimize the potential for adverse drug reactions).

The Alliance also aims to continue educational activities in training students and scientists in biomedical nanotechnology. In doing so, the ANH is developing multi-disciplinary programs for providing training in both basic science and medical research. A summer research program for high-achieving high school students and undergraduates interested in careers in science and/or medicine is in development stages.

Collaborators - Rice University, Baylor College of Medicine, The University of Texas M. D. Anderson Cancer Center, The University of Texas Health Science Center at Houston, The University of Texas Medical Branch at Galveston, Texas A&M University System Health Science Center, The University of Houston, Aptamed, Nanobiomagnetics, Inc., Fairway Medical

Leveraged Dollars – The Texas Emerging Technology Fund awarded the ANH $2.5 million for the recruitment of Dr. Mauro Ferrari to be the ANH President.

Program Name – Advances in Bone Formation and Bone Metastasis

Appropriations –
FY2005
Department of Defense $500,000

Program description – There are more 10 million individuals with osteoporosis and an additional 34 million at high risk. In the United States, osteoporosis is responsible for more than 1.5 million fractures annually with an estimated treatment cost of $18 billion. . Increasing longevity with acceptable quality of life will not be possible unless strategies are developed to maintain skeletal integrity. In addition, 10% of cancer patients will experience metastasis of their cancer to bone, a difficult oncologic problem for which we have not yet developed effective treatment or palliative strategies. Bone destruction occurs in the vast majority (over 80%) of patients with multiple myeloma, a malignancy of plasma cells. The Bone Disease Program of Texas is a collaborative effort between the Baylor College of Medicine and The University of Texas M. D. Anderson Cancer Center, two of the leading research institutions within the Texas Medical Center.

The Department of Defense appropriation in September 2005 was designated for purchase of laboratory equipment for existing laboratories involved in bone research; as this is a collaborative program, the earmarked monies were split between the two entities with approximately half ($248,044) sub-contracted to Baylor. All expenditures from these funds have been approved by the Program Advisory Committee.

The equipment will contribute to the expansion of core laboratories and used by faculty members of the Bone Disease Program of Texas. Analyzing bone requires specialized tools including state-of-the-art microtomes that can reproducibly cut specimens of hard bone. There is also a greater reliance on high-resolution imaging technology. Equipment purchased through this appropriation will enhance the ability of the shared laboratories to sample and image bones in laboratory animals, to obtain quantitative analytical measurements of bone mineral distribution and to perform rapid mining of data thereby enhancing the efficiency and productivity of the participating laboratories.

Collaborators - Faculty from 11 departments at M. D. Anderson and one department at Baylor are participants in the program. This illustrates the multidisciplinary nature of research and patient care for which M. D. Anderson is known.

Measures and Quality - The Bone Disease Program is guided by an oversight panel, which is constituted by leadership from both institutions. These advisory panel members meet regularly and approve all expenditures and activities of the program. The dual representation in leadership fosters transparency in decision-making and development. This oversight extends not only to the earmark funds discussed in this proposal but to all peer-reviewed funding, federal or otherwise. The major expenditures for research grants by the program have been made on a competitive basis. The program has at each point in its development sought external review and advice with the goal of enhancing its competitive position within the field of bone biology.

Leveraged Dollars – The federal appropriation contributed to research advancements, enhancing the Program's ability to raise other funds. The philanthropic goal of this program is to raise 10 million dollars to support this effort, of which approximately 40 percent has been raised. The 2005 federal appropriation for equipment augments NIH grant funding for Bone Program principal investigators of approximately $7.5 million dollars.

Research Accomplishments - Important discoveries in bone biology have been made by members of this program. They include the identification of leptin as a major regulator of bone formation, the studies that have defined the role of the brain and hypothalamus in regulating bone formation and resorption, the identification of two major transcription factors, Runx2 and Osterix, by members of the program, the development of pharmacologic agents that regulate the RANK receptor, the definition of the role of the hormone calcitonin in bone biology, the definition of clock genes in regulation of bone formation, basic studies defining the mechanism by which alkaline phosphatase regulates bone mineralization, and structural studies of vitamin D analogs and their pharmacologic use in treatment of osteoporosis, bone metastasis and other bone disorders.

Publications -

Manuscripts published: 18